

10/530017
Rec'd PCT/PTO 24 APR 2006

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

DECLARATION FOR PATENT APPLICATION

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name.

I believe I am an original, first and joint inventor of the subject matter which is claimed and for which a patent is sought on the invention entitled:

USE OF BIOMARKERS FOR DETECTING ACUTE RENAL TRANSPLANT REJECTION

the specification of which was filed on April 1, 2005 and assigned Application No. 10/530,017.

In the event that the filing date and/or Application No. are not entered above at the time I execute this document, and if such information is deemed necessary, I hereby authorize and request my attorneys/agent(s) at **Edwards & Angell, LLP, P.O. Box 55874, Boston, Massachusetts 02205**, to insert above the filing date and/or Application No. of said application.

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by an amendment, if any, specifically referred to herein.

I acknowledge the duty to disclose all information known to me that is material to patentability in accordance with Title 37, Code of Federal Regulations, § 1.56.

FOREIGN PRIORITY CLAIM

I hereby claim foreign priority benefits under Title 35, United States Code § 119(a)-(d) of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed:

☒ no such foreign applications have been filed

☐ such foreign application have been filed as follows:

Attorney Docket No.: 60022(71699)

**EARLIEST FOREIGN APPLICATION(S), IF ANY FILED WITHIN 12 MONTHS
(6 MONTHS FOR DESIGN) PRIOR TO THIS U.S. APPLICATION**

Application Number	Country	Date of Filing	Priority Claimed Under 35 USC 119
			___ Yes No ___
			___ Yes No ___
			___ Yes No ___

**ALL FOREIGN APPLICATION(S), IF ANY FILED MORE THAN 12 MONTHS
(6 MONTHS FOR DESIGN) PRIOR TO THIS U.S. APPLICATION**

Application Number	Country	Date of Filing

CLAIM FOR BENEFIT OF EARLIER U.S. PROVISIONAL APPLICATIONS

I hereby claim priority benefits under Title 35, United States Code §119(e), of any United States provisional patent application(s) listed below:

☐ no such U.S. provisional applications have been filed.

☒ such U.S. provisional application have been filed as follows:

Application Number	Date of Filing	Priority Claimed Under 35 USC 119
60/507,082	October 1, 2003	<u> x </u> Yes No ___
		___ Yes No ___
		___ Yes No ___

CLAIM FOR BENEFIT OF EARLIER U.S./PCT APPLICATION(S)

I hereby claim the benefit under Title 35, United States Code, §120 of the United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose all information that is material to patentability in accordance with Title 37, Code of Federal Regulations, §1.56 which became

Attorney Docket No.: 60022(71699)

available to me between the filing date of the prior application and the national or PCT international filing date of this application:

☐ no such U.S./PCT applications have been filed.

☒ such U.S./PCT application have been filed as follows:

Application Number	Relationship	Parent Application	Date of Filing
This Application	National Stage	PCT/US03/31089	October 1, 2003

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

I hereby appoint:

All practitioners at Customer Number 49383

all of **Edwards & Angell, LLP**, P.O. Box 55874, Boston, Massachusetts 02205, jointly, and each of them severally, my attorneys at law/patent agent(s), with full power of substitution, delegation and revocation, to prosecute this application, to make alterations and amendments therein, to receive the patent, and to transact all business in the U. S. Patent and Trademark Office connected therewith.

The undersigned hereby authorizes the U.S. attorney or agent named herein to accept and follow instructions from The Johns Hopkins University as to any action to be taken in the United States Patent and Trademark Office regarding this application without direct communication between the U.S. attorney or agent and the undersigned. In the event of a change in the persons from whom instructions may be taken, the U.S. attorney or agent named herein will be so notified by the undersigned.

Please mail all correspondence to Peter F. Corless, whose address is:

Edwards Angell Palmer & Dodge, LLP
P.O. Box 55874
Boston, Massachusetts 02205

Please direct telephone calls to: Peter F. Corless at (617) 439-4444.

Please direct facsimiles to: (617) 439-4170

Attorney Docket No.: 60022(71699)

Attorney Docket No.: 60022(71699)

Full name of sole or first inventor William Clarke	
Sole or first inventor's signature	Date
Residence Columbia, Maryland	
Citizenship US	
Mailing Address 10200 Hickory Ridge Road #103 Columbia, Maryland 21044	

Full name of second inventor, if any Benjamin C. Silverman	
Second inventor's signature <i>Benjamin C. Silverman</i>	Date 4/18/2006
Residence Bel Air, Maryland	
Citizenship US	
Mailing Address 1105 Runnymede Court Bel Air, Maryland 21014	

Full name of third inventor, if any Ernesto P. Moimenti	
Third inventor's signature	Date
Residence Baltimore, Maryland	
Citizenship Argentina	
Mailing Address 2515 Boston Street #402 Baltimore, Maryland 21224	

Full name of fourth inventor, if any Zhen Zhang	
Fourth inventor's signature	Date
Residence Dayton, Maryland	
Citizenship People's Republic of China	
Mailing Address 14104 Big Branch Drive Dayton, Maryland 21036	

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: William Clarke et al.
For: USE OF BIOMARKERS FOR DETECTING ACUTE RENAL
TRANSPLANT REJECTION

the specification of which:

(check and complete (a), (b), or (c))

- (a) ☐ is attached hereto.
(b) ☒ was filed on April 1, 2005, as Application No. 10/530,017 and was amended on _____ (if applicable).
(c) ☐ was described and claimed in International Application No. _____, filed on _____ and as amended on _____ (if any).

STATEMENT OF FACTS IN SUPPORT OF FILING
ON BEHALF OF NONSIGNING INVENTOR (37 C.F.R. SECTION 1.47)

NOTE: This statement as to the pertinent facts concerning the refusal of the nonsigning inventor to join in the application or where the nonsigning inventor cannot be found or reached must accompany the declaration signed on behalf of the nonsigning inventor by a joint inventor or by a legal representative who shows a proprietary interest. Where the entity with a proprietary interest executes the declaration on behalf of the nonsigning inventor there must also be a showing that such action is necessary to preserve the rights of the parties or to prevent irreparable damage. 37 C.F.R. 1.47(a) and (b).

This statement is made as to the exact facts that are relied upon to establish the diligent effort made to secure the execution of the declaration by the nonsigning inventor for the above-identified patent application before deposit thereof in the Patent and Trademark Office.

(check next item, if applicable)

- ☒ Because signing on behalf of the nonsigning inventor is by a person or entity showing a sufficient proprietary interest, this statement also recites facts as to why this action was necessary to preserve the rights of the parties or to prevent irreparable damage.

This statement is being made by the available person having first-hand knowledge of the facts recited therein.

NOTE: The statement "must be signed, where at all possible, by a person having first-hand knowledge of the facts recited therein." M.P.E.P. section 409.03(d), 7th ed. If different persons have first-hand knowledge of different facts, then a declaration from each such person as to those facts he or she knows should be submitted separately.

NOTE: Copies of documentary evidence, such as certified mail return receipt, cover letter of instructions, telegrams, etc., that support a finding that the nonsigning inventor could not be reached should be made part of the affidavit or declaration. It is important that the affidavit or declaration contain statements of fact as apposed to conclusions. M.P.E.P. section 409.03(d), 7th ed.

IDENTIFICATION OF PERSON MAKING THIS STATEMENT OF FACTS

Peter F. Corless (Reg. 33860)
Name of person making statement

Address of person making statement
Edwards Angell Palmer & Dodge LLP
101 Federal Street
Boston, MA 02110

LAST KNOWN ADDRESS OF THE NONSIGNING INVENTOR

NOTE: The last known address of the nonsigning inventor must be stated so that the PTO can forward the notice of filing of the application to the nonsigning inventor at said address. (37 C.F.R. section 1.47) A post office box is insufficient. M.P.E.P. section 409.03(e), 6th ed.

Ernesto Pompeo Molmenti

Full name of nonsigning inventor

2515 Boston Street #402

Baltimore, Maryland 21224

Last known address of nonsigning inventor

NOTE: Ordinarily, the last known address will be the last known residence of the nonsigning inventor, but other addresses at which the nonsigning inventor may be reached should also be given in the space below. M.P.E.P. section 409.03(e), 6th ed.

DETAILS OF EFFORTS TO REACH NONSIGNING INVENTOR

NOTE: Complete either these facts or the facts as to REFUSAL OF NONSIGNING INVENTOR TO SIGN APPLICATION PAPERS.

NOTE: In addition to a recitation of these efforts, which must have been made before the application was deposited in PTO, copies of documentary evidence such as letters, telegrams, responses, etc. that support a finding that a nonsigning inventor could not be found or reached should, if available, be made part of the declaration. It is important that the affidavit or declaration contain statements of fact as opposed to M.P.E.P. section 409.03(d), 7th ed. conclusions.

Please see the attached document entitled:

DETAILS OF NONSIGNING INVENTOR TO SIGN APPLICATION PAPERS

DETAILS OF NONSIGNING INVENTOR TO SIGN APPLICATION PAPERS

NOTE: Complete either these facts or the facts as to DETAILS OF EFFORTS TO REACH NONSIGNING INVENTOR.

NOTE: The circumstances of this refusal must be specified by the person to whom the refusal was made and, before a refusal can be alleged, it must be demonstrated that a bona fide attempt was made to present a copy of the application papers (specification, including claims, drawings and declaration) to the nonsigning inventor for signature. A copy of the application papers should be sent to the last known address of the nonsigning inventor, or, if the nonsigning inventor is represented by counsel, to the address of the nonsigning inventor's attorney. The time and place of an oral refusal should be stated, or a copy of the written refusal should be attached.

Where there is an express oral refusal, that fact along with the time and place of the refusal must be stated in the affidavit or declaration. When there is an express written refusal, a copy of the document evidencing that refusal must be made part of the affidavit or declaration.

If it is the conduct as a whole of the nonsigning inventor that is the refusal, then all the facts upon which this conclusion is based should be stated and a copy of any documentary evidence supporting these facts should be attached.

Where there is an express oral refusal, that fact along with the time and place of the refusal must be stated in the affidavit or declaration. When there is an express written refusal, a copy of the document evidencing that refusal must be made part of the affidavit or declaration.

Whenever the nonsigning inventor gives a reason for refusing to sign the application papers, that reason should be stated. M.P.E.P. section 409.03(d), 7th ed.

Please see the attached document entitled:

DETAILS OF NONSIGNING INVENTOR TO SIGN APPLICATION PAPERS

**PROOF OF NEED TO PREVENT IRREPARABLE DAMAGE
OR PRESERVE THE RIGHTS OF THE PARTIES**

NOTE: This proof must be presented where the declaration is signed by a person with sufficient proprietary interest for the nonsigning inventor (37 C.F.R. section 1.47(b)), but is not a requirement when the person signing for the nonsigning inventor is a joint inventor. (37 C.F.R. section 1.47(a)).

If a statutory bar is involved, the act or publication which is believed to constitute the bar should be identified. If a claim for priority is involved, the prior application or applications should be identified.

A diligent effort to prepare the application and obtain the inventor's signature thereon must be made, even if the application is being filed to avoid a bar or to claim priority. M.P.E.P. section 409.03(g), 7th ed.

Irreparable damage may be established by showing that a filing date is necessary to (1) avoid a statutory bar or (2) make a claim for priority, which should identify the prior application(s) involved.

Preservation of the rights of the parties may be demonstrated by a showing that the nonsigning inventor may reasonably be expected to enter into competition with the person having a proprietary interest and signing on behalf of the nonsigning inventor or that a firm plan for commercialization of the subject matter of the application has been adopted.

M.P.E.P. section 409.03(g), 7th ed.

I, Peter Corless, note the following:

The subject application is a U.S. national entry of PCT/US03/31089 having an international filing date of October 1, 2003 and claiming priority from U.S. Provisional application Serial Number 60/414,647, filed October 1, 2002, thirty months prior to the filing of the subject application.

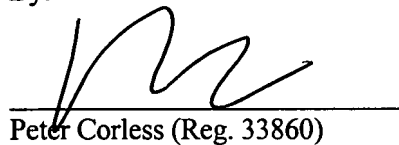
The PCT Receiving Office a Notification of Missing Requirements on September 22, 2005. The final due date, with the maximum allowable extensions, ends on April 24, 2006.

Since the filing of the subject application, Declaration forms have been sent to all the named inventors of the application. All the inventors except Ernesto Molmenti have provided signed Declaration forms to the undersigned attorney.

The undersigned attorney has repeatedly attempted to locate Ernesto Molmenti, but has been unsuccessful in recent attempts. The undersigned is hopeful that Ernesto Molmenti ultimately can be located and a signed Declaration obtained.

Therefore, in order to preserve the rights of the parties in the instant application, the within petition under 37 CFR 1.47 is hereby filed. Grant of the within petition is earnestly requested in order to maintain pendency of the application pending obtaining the signed Declaration from Ernesto Molmenti, and to prevent abandonment of the application which would cause irreparable damage to the parties.

By:



Peter Corless (Reg. 33860)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**DECLARATION FOR PATENT APPLICATION**

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name.

I believe I am an original, first and joint inventor of the subject matter which is claimed and for which a patent is sought on the invention entitled:

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☐ such foreign application have been filed as follows:

Attorney Docket No.: 60022(71699)

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(6 MONTHS FOR DESIGN) PRIOR TO THIS U.S. APPLICATION**

Application Number	Country	Date of Filing	Priority Claimed Under 35 USC 119
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			___ Yes No ___
			___ Yes No ___

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Attorney Docket No.: 60022(71699)

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☒ such U.S./PCT application have been filed as follows:

Application Number	Relationship	Parent Application	Date of Filing
This Application	National Stage	PCT/US03/31089	October 1, 2003

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I hereby appoint:

All practitioners at Customer Number 49383

all of **Edwards & Angell, LLP**, P.O. Box 55874, Boston, Massachusetts 02205, jointly, and each of them severally, my attorneys at law/patent agent(s), with full power of substitution, delegation and revocation, to prosecute this application, to make alterations and amendments therein, to receive the patent, and to transact all business in the U. S. Patent and Trademark Office connected therewith.

The undersigned hereby authorizes the U.S. attorney or agent named herein to accept and follow instructions from The Johns Hopkins University as to any action to be taken in the United States Patent and Trademark Office regarding this application without direct communication between the U.S. attorney or agent and the undersigned. In the event of a change in the persons from whom instructions may be taken, the U.S. attorney or agent named herein will be so notified by the undersigned.

Please mail all correspondence to Peter F. Corless, whose address is:

Edwards Angell Palmer & Dodge, LLP
P.O. Box 55874
Boston, Massachusetts 02205

Please direct telephone calls to: Peter F. Corless at (617) 439-4444.

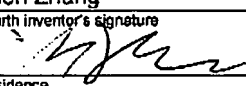
Please direct facsimiles to: (617) 439-4170

Attorney Docket No.: 60022(71699)

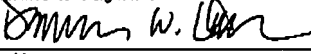
Full name of sole or first inventor William Clarke	
Sole or first inventor's signature	Date
Residence Columbia, Maryland	
Citizenship US	
Mailing Address 10200 Hickory Ridge Road #103 Columbia, Maryland 21044	

Full name of second inventor, if any Benjamin C. Silverman	
Second inventor's signature	Date
Residence Bel Air, Maryland	
Citizenship US	
Mailing Address 1105 Runnymede Court Bel Air, Maryland 21014	

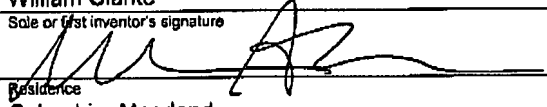
Full name of third inventor, if any Ernesto P. Molmenti	
Third inventor's signature	Date
Residence Baltimore, Maryland	
Citizenship Argentina	
Mailing Address 2515 Boston Street #402 Baltimore, Maryland 21224	

Full name of fourth inventor, if any Zhen Zhang	
Fourth inventor's signature 	Date 4/11/06
Residence Dayton, Maryland	
Citizenship People's Republic of China	
Mailing Address 14104 Big Branch Drive Dayton, Maryland 21036	

Attorney Docket No.: 60022(71699)

Full name of fifth inventor, if any Daniel W. Chan	
Fifth inventor's signature 	Date 4/11/06
Residence Clarksville, Maryland	
Citizenship US	
Mailing Address 12925 Wexford Park Clarksville, Maryland 21029	

Attorney Docket No.: 60022(71699)

Full name of sole or first inventor William Clarke	
Sole or first inventor's signature 	Date 4/11/06
Residence Columbia, Maryland	
Citizenship US	
Mailing Address 10200 Hickory Ridge Road #103 1814 FAUSTAFF COURT Columbia, Maryland 21044 ELWOODBURG, MD 21784	

Full name of second inventor, if any Benjamin C. Silverman	
Second inventor's signature	Date
Residence Bel Air, Maryland	
Citizenship US	
Mailing Address 1105 Runnymede Court Bel Air, Maryland 21014	

Full name of third inventor, if any Ernesto P. Molmenti	
Third inventor's signature	Date
Residence Baltimore, Maryland	
Citizenship Argentina	
Mailing Address 2515 Boston Street #402 Baltimore, Maryland 21224	

Full name of fourth inventor, if any Zhen Zhang	
Fourth inventor's signature	Date
Residence Dayton, Maryland	
Citizenship People's Republic of China	
Mailing Address 14104 Big Branch Drive Dayton, Maryland 21036	